

EXHIBIT 428

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION
4 IN RE: NATIONAL : MDL No. 2804
5 PRESCRIPTION OPIATE :
6 LITIGATION : Case No. 17-md-2804
7 :
8 APPLIES TO ALL CASES : Judge Dan Aaron Polster
9 :
10 :
11 :

12 HIGHLY CONFIDENTIAL
13 SUBJECT TO FURTHER CONFIDENTIALITY REVIEW
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16 DECEMBER 13, 2018

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18 VIDEOTAPED DEPOSITION OF HBC SERVICE COMPANY'S
19 DESIGNATED 30(B)(6) REPRESENTATIVE,
20 JAMES TSIPAKIS,
21 taken pursuant to notice, was held at Marcus & Shapira,
22 One Oxford Center, 35th Floor, Pittsburgh, Pennsylvania
23 15219, by and before Ann Medis, Registered Professional
24 Reporter and Notary Public in and for the Commonwealth
25 of Pennsylvania, on Thursday, December 13, 2018,
commencing at 9:09 a.m.

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1 Q. What information, reports, data is
2 available to those pickers to allow them to
3 identify patterns that deviate from the norm?

4 A. I did not find any particular reports or
5 any specific things that they were looking for.

6 Q. With Mr. Durr, the superintendent, can
7 you kind of generally describe for me what his job
8 duties were on a daily basis?

9 A. His responsibilities would be the
10 security and controls of running our pharmacy
11 warehouse.

12 Q. And that pharmacy warehouse included not
13 only the Schedule III hydrocodone combination
14 products that we've been talking about today, but
15 it also included a variety of other prescription
16 medication; correct?

17 A. Nonscheduled, is that what you're
18 asking?

19 Q. Sure.

20 A. Yes.

21 Q. It also included Schedule IVs and
22 Schedule Vs; correct?

23 A. Correct.

24 Q. It included Schedule IIIs that are not
25 hydrocodone combination products; correct?

1 A. Yes.

2 Q. It also included I think, as you just
3 said, noncontrolled substances such as blood
4 pressure medicine, acne medication, birth control.
5 All those types of things would be included;
6 correct?

7 A. Yes.

8 Q. And all those things are under the
9 purview of Mr. Durr; correct?

10 A. Yes.

11 Q. Are you aware of any data, reports or
12 information that Mr. Durr had available to him to
13 assist him in identifying any patterns of Schedule
14 III drug orders, specifically HCPs, that would
15 have deviated from the norm?

16 A. Through this process I did not find
17 any -- you keep asking me reports. I did not find
18 any reports that he'd be looking at. But, again,
19 as part of this integrated process, he would be
20 working with our operations folks. The operation
21 folks oversee the stores. So it's a closed
22 system. So there's a negative feedback loop
23 within that system.

24 Q. And I'm not trying to ask a question
25 that I already know the answer to. I'm just

1 trying to be inclusive when I say data, report
2 information --

3 A. Sure. And I'm trying to do my best to
4 answer what it is you're looking for.

5 Q. I understand. But I didn't want you to
6 get focused on the word reports. You're not aware
7 of any information, data that Mr. Durr had
8 available to him to assist him with identifying
9 patterns that deviated from the norm?

10 A. What I'm saying is I don't have -- other
11 than written documents, I don't have -- I'm not
12 privy to the conversations and the pieces and the
13 things that he did as part of running his
14 warehouse.

15 Q. When you got information from Mr. Durr,
16 he didn't say, I had this report to review or I
17 had this dataset that I got sent to me on a
18 regular basis. He didn't say anything like that?

19 A. I didn't read any of that, no.

20 Q. I'm going to ask you the same questions
21 as it relates to Mr. Carlson and the other folks
22 that would have been in procurement.

23 Are you aware of any data, information,
24 reports that they had available to them to assist
25 them in identifying any patterns of HCPs ordering

1 that would have deviated from the norm?

2 A. Certainly the folks in corporate would
3 have information on what's being purchased by our
4 stores and certainly feedback from the operations
5 team that oversee these stores. But through this
6 process, I didn't have any specific reports or
7 documented -- I go back to reports because we're
8 not privy to the conversations and to how they did
9 their job or didn't do their job on a day-to-day
10 basis from what I could read.

11 Q. I understand. What I hear you to be
12 saying is the information you got from
13 Mr. Carlson, who was one of the procurement folks
14 during this timeframe, was that he didn't inform
15 you of any data, reports or information that he
16 was provided on a regular basis for him to review
17 orders to see whether or not there was a pattern
18 that deviated from the norm?

19 MR. BARNES: You mean other than what
20 he's testified to?

21 MR. GADDY: I asked the question.

22 MR. BARNES: Object to form. Asked and
23 answered.

24 THE WITNESS: What I'm saying is through
25 what I reviewed from Mr. Carlson, I couldn't

1 ascertain what he used or didn't use to do this
2 job.

3 BY MR. GADDY:

4 Q. There was no paper identified, no
5 report, no Excel spreadsheet, nothing like that
6 that was identified by Mr. Carlson, Mr. Durr or
7 any information you received from the pickers, no
8 documents that were identified that were reviewed
9 to assist with this process; correct?

10 A. Specifically, again, our system
11 continued to be improved and changed over time.
12 And there were certainly procedures that were
13 buttressed and improved over time. But certainly
14 through what I read, there was nothing on a report
15 or, to your point, Excel spreadsheet that I did
16 glean. It doesn't mean there wasn't any. It
17 wasn't in what I had read.

18 Q. You spent 40 to 50 hours preparing for
19 today; correct?

20 A. Yes, sir.

21 Q. You made every effort to get all the
22 information you could; correct?

23 A. Yes.

24 Q. You mentioned that the system had
25 improvements over time.

1 A. Yes.

2 Q. I think you said that at some point in
3 time, there was a threshold program implemented?

4 A. Yes.

5 Q. When did HBC first start utilizing a
6 threshold program?

7 A. A threshold program with some IT
8 enhancements were put into place roughly in 2013.

9 Q. Do you know what month in 2013 or season
10 even?

11 A. I don't recall exactly in 2013.

12 Q. And were thresholds set for every
13 prescription drug or just controlled substances?

14 A. Controlled substances.

15 Q. And that included Schedule III
16 controlled substances?

17 A. Yes.

18 Q. How were thresholds established? Let me
19 back up before you answer that. I'm making an
20 assumption that threshold is a monthly ordering
21 threshold. Am I wrong on that?

22 A. So the threshold established was using
23 diligence that was ascertained at the time from
24 DEA that a 3X threshold to be established, a
25 monthly threshold, to your point, using 12 months

1 of trailing data, 3X the average for that month.

2 Q. Let me say it back to you to make sure I
3 understand it. This threshold program which was
4 first begun in 2013 set a threshold at 3 times the
5 average amount of that substance that was
6 distributed over the last 12 months?

7 A. So 3X the company average for that
8 chemical. So it was at the GPI level. So the
9 chemical would include all the drugs having that
10 chemical in it, 3X using 12 months of trailing
11 data, 3X the company average for that chemical,
12 that product.

13 Q. So you explained two things there.
14 First of all, it was based on the chemical?

15 A. GPI level, yes.

16 Q. Does that mean that Lortab and Vicodin
17 don't get different thresholds. They're all under
18 the same threshold?

19 A. It's all lumped together as one
20 threshold.

21 Q. Because that's the same combination of
22 hydrocodone and acetaminophen?

23 A. It's looking at the active ingredient,
24 yes.

25 Q. As far as how the threshold is set, if

1 HBC had sold a hundred HCP products over a month
2 for the last 12 months, the threshold for the next
3 month would have been 300; is that fair?

4 A. Well, the threshold was -- yes. Let me
5 just play that back. So it would be 3X again at
6 the GPI level of that GPI using the 12 months
7 worth of data, yes.

8 Q. So months 1 through 12 Giant Eagle
9 pharmacies had ordered 100 hydrocodone combination
10 products?

11 A. All included.

12 Q. Correct. Then in month 13 the threshold
13 would be 300?

14 A. Well, it uses the average of the 12
15 months of data. When the new month comes on, the
16 furthest out drops off. It's a rolling 12 months
17 worth of data, yes.

18 Q. But I have that math right, in month 13,
19 the threshold would be 300 because the prior 12
20 months, the average was 100?

21 A. But again, it uses the last 12 months.
22 So assuming that it was a hundred all those
23 months, it would be 3X which would be 300, yes.

24 Q. You said it was a rolling system. So at
25 the 13th month, instead of HBC distributing a

1 hundred HCPs and it distributed 200, the threshold
2 for the 14th month would be different. It would
3 not be the same 300 because that last month would
4 have affected the average; correct?

5 A. Each datapoint adds to the average. And
6 certainly the reason for that is there's
7 seasonality in our business as well where products
8 change over time, yes. The demand for products
9 change over time.

10 Q. When you say seasonality, do you mean
11 different times of years or do you mean --

12 A. Yes. Different times of year, cough and
13 cold season versus summer months, yes.

14 Q. Is there a hydrocodone combination
15 product season?

16 A. Well, certainly hydrocodone products in
17 cough syrups, it is more prevalent during cough
18 and cold season than it is during summer months.

19 Q. I think I heard you mention that HBC
20 received guidance from the DEA that a 3 times
21 average was an appropriate threshold.

22 A. What I said is during the due diligence
23 to set the threshold, information was derived from
24 the DEA published websites on a 3X threshold that
25 they used for list chemicals, and that's where our

1 3X number was derived from.

2 Q. You're talking about the chemical
3 handler's manual?

4 A. From what I -- to prepare for this, it
5 was based on written DEA inference on a website or
6 a manual, I'm not sure where it was derived from,
7 but the DEA itself was establishing a 3X
8 threshold, and the team adopted that rationale.

9 Q. Are you testifying that the DEA had
10 suggested a 3X threshold for opioids?

11 A. I'm testifying that the HBC warehouse
12 and the team involved found data that pointed to a
13 3X threshold tier, and that's what they adopted.

14 Q. But for opioids. That's my question.
15 Are you testifying that HBC had information from
16 the DEA that they were approving or ratifying or
17 blessing, whatever verb you want to use, a 3X
18 threshold in 2013 for opioids?

19 A. No. That is not what I'm saying.

20 Q. Then help me understand.

21 A. What I'm saying is in the diligence to
22 set the threshold, Giant Eagle inferred from
23 information that they gleaned from the website, a
24 manual, whatever it was, that established a 3X
25 threshold is where they want -- the DEA was -- the

1 DEA over the years has not been clear about what
2 their expectations were of any threshold.

3 So it left each registrant to set whatever
4 parameters and controls that they deemed
5 appropriate. So our team used whatever they could
6 find that was reasonably available and reasonable
7 to set our thresholds.

8 Q. The DEA never told HBC that a three
9 times average was appropriate; correct?

10 A. Directly, no, never.

11 Q. Did DEA indirectly tell HBC that a three
12 times average was appropriate?

13 A. What I'm saying is the HBC set its
14 threshold based on information that it gleaned
15 from a DEA -- just like you showed me earlier, a
16 page from the DEA website. There was information
17 that they used from DEA and inferred to use a 3X
18 threshold.

19 HBC set the threshold, but it wasn't just
20 some arbitrary number they picked. There was
21 information they used to get to a 3X threshold.

22 Q. I'll show you what I'll mark as No. 13.

23 (HBC-Tsipakis Exhibit 13 was marked.)

24 BY MR. GADDY:

25 Q. I'm showing you a June 2, 2012 letter

1 from Joe Rannazzisi with the DEA. Do you see
2 that?

3 A. Yes.

4 Q. Have you ever seen this before?

5 A. Yes.

6 Q. Did you have the opportunity to review
7 this document in preparing for your deposition
8 today?

9 A. Not all of it.

10 Q. I'll represent to you and you can flip
11 through it and we'll look through some of this,
12 but it's a 2012 letter, and attached to that
13 letter were earlier letters, two from 2007 and one
14 from 2006.

15 Do you see that?

16 A. Yes.

17 Q. And are you aware that HBC received this
18 letter?

19 MR. BARNES: Just the one on top or all
20 of them?

21 MR. GADDY: The one at the top with the
22 attachments.

23 THE WITNESS: I'm not aware of whether
24 HBC received these letters or not. As a matter of
25 common sense, we weren't registered in 2007. So I

1 would assume that we wouldn't have gotten that
2 since we weren't a registrant, and this states
3 that it went to the registrants.

4 The only one, and I don't know if we did or
5 did not receive it, would have been this one from
6 2012.

7 BY MR. GADDY:

8 Q. This one in 2012 was before HBC
9 instituted its threshold policy at three times
10 average; correct?

11 A. Yes.

12 Q. And it says -- in the first line, it
13 says, "This letter is being sent to every entity
14 in the United States who is registered with the
15 Drug Enforcement Administration to manufacture or
16 distribute controlled substances."

17 Do you see that?

18 A. Yes.

19 Q. In June 2012, was HBC such a registrant?

20 A. Yes.

21 Q. "This letter is to remind controlled
22 substance manufacturers and distributors of their
23 responsibilities to inform the DEA of suspicious
24 orders in accordance with 21 CFR 1301.748."

25 Do you see that?